IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SHIRE ORPHAN THERAPIES LLC and SANOFI-AVENTIS DEUTSCHLAND GMBH,	)	
Plaintiffs,	)	
v.	)	C.A. No. 15-1102 (GMS)
FRESENIUS KABI USA, LLC,	)	
Defendants.	)	

AMENDED FINAL JUDGMENT

Whereas this action came before the Court for a bench trial beginning on January 29, 2018, the issues have been tried, and a decision was rendered by the Court on June 5, 2018;

IT IS HEREBY ORDERED AND ADJUDGED that final judgment is hereby entered in favor of:

1. Plaintiffs (SHIRE ORPHAN THERAPIES LLC and SANOFI-AVENTIS DEUTSCHLAND GMBH), and against Defendant (FRESENIUS KABI USA, LLC), finding that the asserted claim of the patent-in-suit (Claim 14 of U.S. Patent No. 5,648,333) is not invalid due to obviousness-type double-patenting for the reasons set forth in the Court's Memorandum (D.I. 115) and Order (D.I. 116).

2. Plaintiffs, and against Defendant, finding that the asserted claim of the patent-in-suit is not unenforceable for prosecution laches for the reasons set forth in the Court's Memorandum (D.I. 115) and Order (D.I. 116).

3. Plaintiffs, and against Defendant, finding that the icatibant acetate product that is the subject of Abbreviated New Drug Application 208317 ("Defendant's ANDA") (including any amendments or supplements thereto), as well as the active ingredient contained therein,

infringes claim 14 of U.S. Patent No. 5,648,333 ("the '333 patent") under 35 U.S.C. § 271(e), and if Defendant commercially manufactures, uses, markets, or sells the product that is the subject of Defendant's ANDA, or offers that product for sale within the U.S., or imports that product into the United States, Defendant would infringe the asserted claim as stipulated by the parties (D.I. 75).

IT IS HEREBY FURTHER ORDERED that, under 35 U.S.C. § 271(e)(4)(A), the effective date of any final approval by the FDA of Defendant's ANDA shall not be on or before July 15, 2019, which is the Orange-Book listed expiration date of U.S. Patent No. 5,648,333, and it is further

ORDERED that, should Defendant's ANDA receive final FDA approval prior to the date of this Order, that approval is hereby converted to tentative approval, and shall not be on or before July 15, 2019, which is the Orange-Book listed expiration date of the '333 patent; and it is further

ORDERED that, under 35 U.S.C. § 271(e)(4)(B), Defendant, as well as its officers, agents, servants, employees, attorneys, and those persons in active concert or participation with them, are permanently enjoined from commercially manufacturing, using, selling, or offering to sell within the United States, or importing into the United States, the product that is the subject of Defendant's ANDA, including any amendments or supplements thereto, for the term of the '333 patent; and it is further

ORDERED that, any motion for costs or attorney fees shall be filed within the timeframe provided in D. Del. LR 54.1 and Fed. R. Civ. P. 54(d); and it is further

ORDERED that, all pending motions and other outstanding requests for relief not specifically addressed herein are DENIED AS MOOT.

Dated: June 25, 2018

JUDGE GREGORY M. SLEET
UNITED STATES DISTRICT JUDGE